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10/686,507	10/14/2003	Bernard Andreas	021629-001900US	3531

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TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER
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OU, JING RUI

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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01/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/686,507	<b>Applicant(s)</b> ANDREAS ET AL.	
	<b>Examiner</b> JING OU	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/23/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This action is responsive to the amendment on October 23, 2008. Claims 1-20 are pending. Claims 1 and 11 are independent. Claims 4 and 14 are withdrawn from consideration.

#### ***Information Disclosure Statement***

2. The information disclosure statement filed 10/23/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Claim Rejections - 35 USC § 103***

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-2, 5-12, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589).

In regard to claim 1-2, 5-12, 15-18 and 20, Chermoni discloses:

A) a stent delivery device for delivering a plurality of stent segments to a treatment site, the device comprising: a catheter shaft (124, Fig. 1) having a proximal end and a distal end; an expandable member (balloon, 104, Fig. 7) coupled with the catheter shaft near the distal end; a shuttle (carriage, 605, Fig. 7) disposed coaxially over at least part of the catheter shaft and the expandable member, at least part of the shuttle being radially expandable (Para. [0042]); and a plurality of stent segments (distal and proximal segments of stents 206a, 206b, and 206c, Fig. 7 and see Figure below or Para.[0004]) having a radially collapsed configuration and a radially expanded configuration, the stent segments disposed along the shuttle and advanceable therealong such that adjacent stent segments may be advanced along the shuttle into direct engagement with one another in the collapsed configuration (the distal and proximal segments of stent 206a, 206b, or 206c are adjacent to each other and are in direct engagement with one another in the collapsed configuration. They are capable to advance along the shuttle);

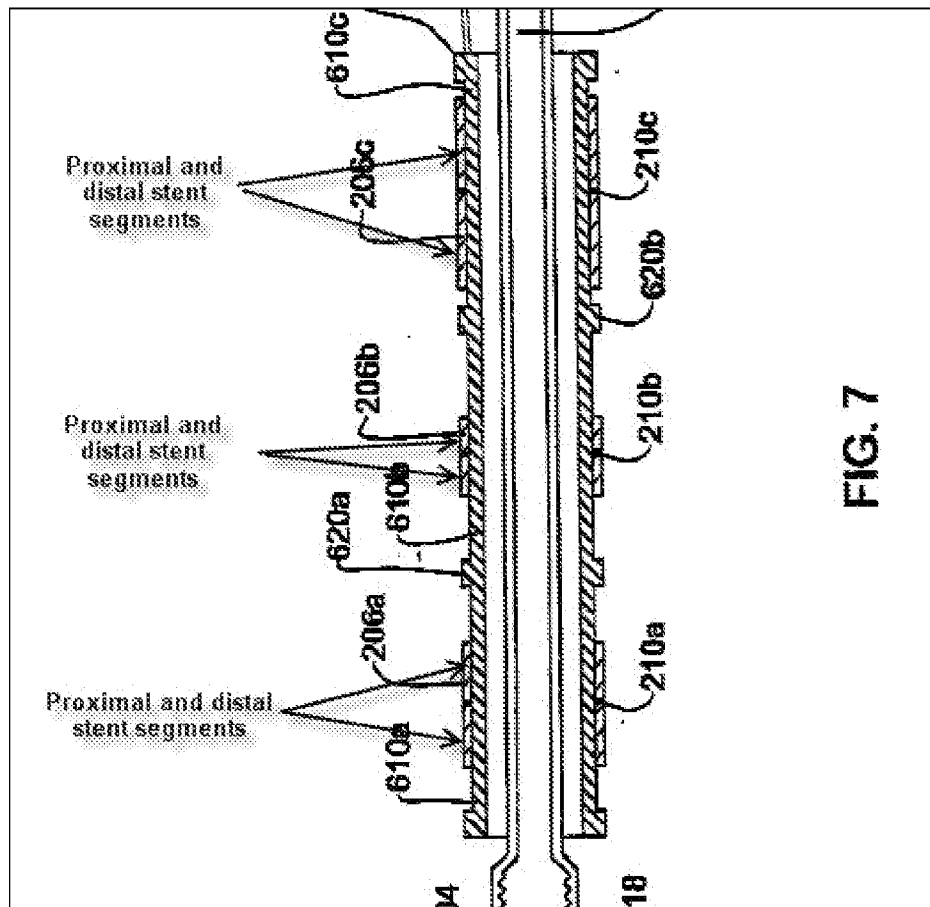
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B) the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member (Para. [0041]);

C) the stent segments are fixed to the shuttle until they are expanded into a deployed position (Paras.[0041]-[0042]);

D) the stent segments are slidable (Para.[0041]), the device further comprising a stent-pushing member (106, Fig. 7), proximal to the plurality of stent segments.

E) the shuttle further comprises an abutment (barrier, next to 610a, Fig. 7) at or near a distal end of the shuttle for preventing the plurality of stent segments from being advanced beyond the distal end of the shuttle;



Chermoni does not appear to disclose:

- A) an axially movable sheath disposed over at least part of the catheter shaft and the expandable member and moving the sheath axially toward the proximal end of the catheter shaft allows at least part of the expandable member to expand against the shuttle to cause the shuttle to radially expand, thus causing at least one of the plurality of stent segments to expand; the sheath having a reinforced distal portion; and
- B) a sheath disposed over the shuttle.

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The recitations, “adapted to resist radial expansion of the expandable member ” and “ while a remaining portion of the expandable member is constrained by the sheath” in Claim 1; “the sheath is adapted to expose a first portion of the expandable member to deploy a first selected number of stent segments” in Claim 6; and “the sheath is adapted to further expose at least a second portion of the expandable member to deploy a second selected number of stent segments” in Claim 7; are intended use recitations. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim limitation.

However, Keith et al explicitly teach:

A) an axially movable sheath (delivery sheath, 60R, Fig. 11) disposed over at least part of the catheter shaft (lead balloon catheter, 68R, Fig. 4) and the expandable member (balloon, 70R, Fig. 4) and moving the sheath axially toward the proximal end of the catheter shaft allowing at least part of the expandable member to expand, thus causing a stent (aortic stent, 64R, Fig. 4) to expand (Col. 12, lines 48-51, the expansion of the balloon causes the stent to expand); and the sheath having a reinforced distal portion (Col. 6, lines 65-67 and Col. 7, lines 1-2, Keith et al discloses a sheath having a reinforced layer throughout the sheath);

B) the sheath is disposed over the distal portion of the outer shaft of catheter that carries the stent (Figs. 4 and 11); and

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C) a plurality of stent segments with adjacent stent segments in direct engagement with one another (adjacent struts of the stent 64R, Fig. 27).

In addition, the sheath of Keith et al meets the functional limitation, "a remaining portion of the expandable member is constrained by the sheath." (Col. 7, lines 6-11 and Figs. 10-13)

Chermoni and Keith et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni and Keith et al before him or her, to modify the stent delivery device of Chermoni to include an axially movable sheath and replace the stent push member of Chermoni by a pusher tube (ledge, 72, Fig. 4) as taught by Keith et al.

The suggestion/motivation for modifying a sheath to include a reinforced layer would have been to add column strength or kink resistance (Col. 6, lines 65-67 and Col. 7, lines 1-2). Applicant should note that it is well-known in the art that an axial movable sheath is used to keep a stent to remain unexpanded and prevent a stent from deploying at an undesired location. It is also well-known that a pusher tube/ledge is used to push the stent out a sheath.

Therefore, it would have been obvious to combine Keith et al with Chermoni to obtain the invention as specified in the instant claims.

6. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.:

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6,070,589) as applied to claims 1 and 11 above, and further in view of Shaknovich (US Pat. No.: 5,807,398).

In regard to claims 3 and 13, Chermoni and Keith et al disclose all the limitations of the claim as taught above but fail to disclose that the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member.

However, Shaknovich explicitly discloses a shuttle (1, Fig. 1) that is fixedly disposed over at least part of the catheter shaft (7, Fig. 1) and the expandable member (8, Figs 1 and 4 and Col. 4, lines 22-31).

Chermoni, Keith et al, and Shaknovich are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teaching of Chermoni, Keith et al, and Shaknovich before him or her to modify the stent delivery device of Chermoni and Keith et al to include a shuttle that is fixedly disposed over at least part of the catheter shaft and the expandable member of Shaknovich.

The motivation/suggestion for doing so would have been to be advanced into a patient as a shuttle-balloon catheter assembly (Shaknovich, Col. 11, lines 1-16).

Therefore, it would have been obvious to combine Shaknovich with Chermoni and Keith et al to obtain the invention as specified in the instant claims.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.:

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6,070,589) as taught in Claim 11, and further in view of Martinez et al (US Pat. No.: 5,593,412).

In regard to Claim 19, Chermoni in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Martinez et al explicitly discloses valve members coupled with the sheath (51-55, Fig. 2B).

Chermoni, Keith et al, and Martinez et al are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Keith et al and Martinez et al before him or her, to modify the stent delivery device of Chermoni in view of Keith et al to include the valve members coupled with the sheath as taught by Martinez et al., because it is well-known in the art that the valve members coupled with the sheath keep the stent from premature deployment.

Therefore, it would have been obvious to combine Martinez et al with Chermoni and Keith et al to obtain the invention as specified in the instant claim.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chermoni (US Pub. No.: 2002/0156496 A1) in view of Keith et al (US Pat. No.: 6,070,589) as taught in Claim 11, and further in view of Palermo (US Pat. No.: 5,312,415)

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In regard to Claim 19, Chermoni in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

Chermoni, Keith et al, and Palermo are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Chermoni in view of Keith et al and Palermo before him or her, to modify the stent delivery device of Chermoni in view of Keith et al to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Chermoni and Keith et al to obtain the invention as specified in the instant claim.

9. Claims 1-3, 5-9, 11-13, 15-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589).

In regard to Claims 1-3, 5-9, 11-13, 16-17, and 20, Shaknovich discloses a stent catheter system, comprising: a catheter shaft (7, Fig. 4), an expandable member (balloon, 8, Fig. 4), an axially movable sheath (13, Fig. 6), a shuttle (1, Fig. 1), a plurality

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of stent segments (3a, Fig. 9); wherein the outer surface of the shuttle is free of surface features that prohibit positioning of a stent segment along the outer surface, and wherein the outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direction engagement with one another (the outer surface of the shuttle 1 is free of surface features that prohibit positioning of a stent segment along the outer surface. The outer surface of the shuttle is adapted to allow a pair of adjacent stents to be positioned into direct engagement with one another because a pair of adjacent stent can be positioned into direct engagement with one another when a second stent of the pair of adjacent stent is deployed on inner side of a first stent of the pair of adjacent stent at the same location after the first stent is deployed on the blood vessel), wherein the shuttle is slidably disposed over at least part of the catheter shaft and the expandable member when the expandable member is deflated, the shuttle is fixedly disposed over at least part of the catheter shaft and the expandable member when the expandable member is inflated, the stent segments are fixed to the shuttle until they are expanded into a deployed position, and the stent segments are slidably disposed along the shuttle when the expandable member is deflated.

Shaknovich fails to explicitly disclose that the sheath has a reinforced distal portion and a stent-pushing member.

However, Keith et al teaches a stent delivery system, comprising: a sheath (delivery sheath, 60R, Fig. 11) having a reinforced distal portion (Col. 6, lines 65-67 and Col. 7, lines 1-2, Keith et al discloses a sheath having a reinforced layer throughout the sheath) and a stent-pushing member (ledge, 72R, Fig. 4).

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Shaknovich and Keith et al are analogous art because they are from the same field of endeavor.

Therefore, it would have been obvious to combine Keith et al with Shaknovich to obtain the invention as specified in the instant claims. The suggestion/motivation for modifying the sheath of Shaknovich to include a reinforced layer as taught by Keith et al would have been to add column strength or kink resistance (Keith et al, Col. 6, lines 65-67 and Col. 7, lines 1-2). Applicant should have noted that it is old and well-known that a pusher tube/ledge located on the proximal end of a stent is used to push the stent out a sheath.

10. Claims 10 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claims 1 and 11 above, and further in view of Chermoni (US Pub. No.: 2002/0156496).

In regard to Claims 10 and 18, Shaknovich in view of Keith et al discloses all the limitations of the claims but fails to teach an abutment at or near a distal end of the shuttle.

However, Chermoni explicitly teaches an abutment (the protrusion/barrier at the most distal end of the carriage/shuttle 605 as shown in Fig. 6) at or near a distal end of the shuttle.

Therefore, it would have been obvious to combine Chermoni with Shaknovich and Keith et al to obtain the invention as specified in the instant claims. Applicant should have noted that it is old and well-known that such abutment would have been to

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provide a barrier to prevent the stent segments from being advanced beyond the distal end of the shuttle.

11. Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich (US Pat. No.: 5,807,398) in view of Keith et al (US Pat. No.: 6,070,589) as applied to claim 11 above, and further in view of Palermo (US Pat. No.: 5,312,415)

In regard to Claim 19, Shaknovich in view of Keith et al discloses all the limitations the claim as taught above but fails to disclose at least one valve member coupled with the sheath for selectively retaining at least one stent segment within the sheath.

However, Palermo explicitly discloses a sheath with a constricted distal end (104, Fig. 1).

Shaknovich, Keith et al, and Palermo are analogous art because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Shaknovich in view of Keith et al and Palermo before him or her, to modify the stent delivery device of Shaknovich in view of Keith et al to include a sheath with a constricted distal end as taught by Palermo.

The suggestion/motivation for doing so would have been to control the discharge of the coil/ stent /vascular device through the catheter sheath distal tip (Palermo, Col. 3, lines 67-68 and Col. 4, lines 1-3)

Therefore, it would have been obvious to combine Palermo with Shaknovich and Keith et al to obtain the invention as specified in the instant claim.

***Response to Arguments***

12. Applicant's arguments filed 10/23/2008 have been fully considered but they are not persuasive. The allegation on pages 7-11 of the remarks that neither Chermoni nor Keith teaches or suggest a plurality of stent segments having a radially collapsed configuration and a radially expanded configuration, the stent segments disposed along the shuttle and advanceable therealong such that adjacent stent segments may be advanced along the shuttle into direct engagement with one another in the collapsed configuration is incorrect. Chermoni discloses a plurality of stent segments (distal and proximal segments of stents 206a, 206b, and 206c, Fig. 7 and see Figure above or Para.[0004]) having a radially collapsed configuration and a radially expanded configuration, the stent segments disposed along the shuttle and advanceable therealong such that adjacent stent segments may be advanced along the shuttle into direct engagement with one another in the collapsed configuration (the distal and proximal segments of stent 206a, 206b, or 206c are adjacent to each other and are in direct engagement with one another in the collapsed configuration. They are capable to advance along the shuttle). In addition, Keith discloses a plurality of stent segments with adjacent stent segments in direct engagement with one another (adjacent struts of the stent 64R, Fig. 27)

***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773

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